

## **I. Restriction Requirement and Election**

The Office requires restriction between Groups I and II:

I. Claims 13, 60-76, 78, 79, and 82-87, drawn to a method for screening compounds capable of binding to G protein-coupled receptors by subjecting a yeast host cell comprising a constitutively active heterologous G-protein-coupled receptor to a test compound and measuring cell growth.

II. Claims 26, 52-59, 70-76, 78, 79, and 81-87, drawn to a method for screening compounds capable of binding to G protein-coupled receptors by subjecting a yeast host cell to a test compound and measuring cell growth, the yeast host cell comprising a constitutively active heterologous G-protein-coupled receptor, as well as an additional mutation of the host cell gene that results in an improved functional response. *Id.*

According to the Office the inventions of Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The first claimed invention allegedly "lacks a special technical feature because it fails to distinguish the claimed invention from the prior art" (*id.*, page 3), specifically, Clark et al., J. Biol. Chem., 12:8831-8841 (1994)). The Office states that Clark "discloses a yeast host cell comprising a constitutively-active G-protein coupled receptor that meets the limitations of the G-protein coupled receptor recited in the first claimed invention." *Id.* Although the claim is directed to a method of screening compounds and not to a yeast cell, the Office contends that "[c]laim 13 is anticipated by prior art." *Id.* Thus, the Office

concludes, "claim 13 lacks a special technical feature and cannot share one with the other claims." *Id.*

The Office also imposes species election requirements. If Applicants elect Group I, they are required to elect (1) a species of heterologous receptor from a list of 18 receptors provided on page 4 of the Office action, and (2) a species of chimeric G alpha protein from the list of 12 chimeric G alpha proteins provided on page 5 of the Office action. If Applicants elect Group II, they are required to elect (1) a species of heterologous receptor from a list of 4 receptors provided on page 5 of the Office action, (2) a species of mutated host cell gene from the list of 10 mutated host cell genes listed on page 6 of the Office action, and (3) a species of chimeric G alpha protein from the list of 12 chimeric G alpha proteins provided on pages 6 and 7 of the Office action.

Applicants traverse the restriction and species election requirements. Applicants elect Group I, claims 13, 60-76, 78, 79, and 82-87, with traverse. For the species of heterologous receptor, Applicants elect the human alpha 2A adrenergic receptor, with traverse. For the species of chimeric G alpha protein, Applicants elect Gai2, with traverse. The elected species read on claims 13, 60-66, 70-76, 78, 79, and 82-87

## **II. Traversal**

In the Decision on Petition mailed May 2, 2006, the Director of Technology Center 1600 stated: **The application will be forwarded to the examiner for further consideration of applicants' reply and further action not inconsistent with this decision.** Decision on Petition, page 3. The restriction requirement imposed in the Office action mailed July 24, 2009, is inconsistent with Director LeGuyader's decision on Applicants' petition and contrary to his instruction to the Examiner.

Applicants present a brief summary of the pertinent events in this application:

1. **25 March 2002:** First restriction requirement mailed.
2. **10 May 2002:** Applicants file a response to restriction requirement.
3. **9 September 2002:** Second restriction requirement mailed; vacates first restriction requirement. Claims 13 and 26 were placed into Group II.
4. **7 February 2003:** Applicants file amendment and response to restriction requirement, electing Group II claims 13 and 26. Applicants amended claim 13 and 26 to convert them from dependent to independent claims. In addition, Applicants requested entry of claims 52-85, which with the exception of claim 81, each depended from claims 13 and 26. All of the claims pending after entry of the Amendment (13, 26, and 52-85) were directed to a method of screening compounds that bind to a G protein-coupled receptor to cause cell growth. In other words, they were all directed to what the Office asserted constituted Group II.
5. **22 April 2003:** Third restriction requirement mailed, alleging the claims constitute nine patentably distinct inventions. Notably, claims 13 and 26 are split into two groups. Claim 13 is put in Group I and claim 26 is put in Group II.
6. **22 September 2003:** Applicants file a response to restriction requirement, with traverse.
7. **21 January 2004:** Notice of noncompliance mailed.
8. **23 September 2004:** Office action mailed, which vacates the notice of noncompliance. Restriction requirement made final. Claims 26, 52, 57-80, 82, 83, and 85 examined. Claims were objected to as reading on non-elected invention.

9. **22 March 2005:** Applicants file amendment and request for reconsideration. Applicants request that objection to claims be held in abeyance pending filing petition seeking review of third restriction requirement.
10. **12 July 2005:** Communication mailed asserting amendment was not responsive because objection may not be held in abeyance.
11. **11 January 2006:** Applicants file supplemental amendment in response to 12 July 2005 communication amending claims to remove subject matter that was not elected in response to third restriction requirement.
12. **11 January 2006:** Applicants file petition under Rules 1.144 and 1.181 seeking withdrawal of third restriction requirement.
13. **2 May 2006:** Decision on Petition is mailed. Director LeGuyader states in the Decision:

That a second Lack of Unity holding was made is perhaps understandable due to change of examiners, but it is not normally done. That the second examiner then made an additional Lack of Unity holding following additional of dependent claims is not conducive to the compact prosecution desired by the Office and applicants. Upon review of the holding it is clear that the holding should, at most, have been considered a request for an election of species, not a Lack of Unity holding, based on the fact that applicants have now claimed specific species within the elected Group which were not previously claimed, and it will be so construed. Applicants have complied and elected a species on which prosecution has proceeded. Should the elected species be found allowable over the art, the examiner will follow the guidelines in M.P.E.P. 803.02 for consideration of other species.

Decision, page 3. Director LeGuyader also states that “[t]he application will be forwarded to the examiner for further consideration of applicants’ reply and further action not inconsistent with this decision.”

**14: 14 June 2006:** Applicants file supplemental amendment that reverts the claims to the scope they had prior to entry of the supplemental amendment filed 11 January 2006. There was no need for Applicants to amend the claims as they did via the 11 January 2006 amendment because the Examiner's restriction requirement was improper.

**15: 18 August 2006:** Communication mailed providing guidance on claim scope following election in view of a restriction. The communication imposes no duty on Applicants to take any action, nor sets a time period for taking action.

**16: 5 April 2007:** Office mails notice of abandonment for failure to response to the communication mailed 18 August 2006.

**17: 8 June 2007:** Applicant filed petition to revive unintentionally abandoned application.

**18: 24 April 2009:** Office mails corrected decision on petition granting the petition and vacating the 18 August 2006 communication for having insufficient examination and notice of time for prosecution.

**19: 24 July 2009:** Office mails the instant Office action and restriction requirement.

**20: 22 January 2010:** Applicants file this response.

In this fourth restriction requirement, the Office is again imposing the same lack of unity holding as a basis for requiring applicants to elect between claims 13 and 26 that was expressly reversed in the Decision on Petition. The Office alleges that the current claims are different and thus the restriction is proper. The claims, however, have the same scope as when the Office imposed the third restriction requirement.

There is no basis for imposing the restriction. For the reasons set forth in Applicants' granted petition filed 11 January 2006, the Office should withdraw the restriction requirement. The requirement is flatly inconsistent with the Decision on Petition.

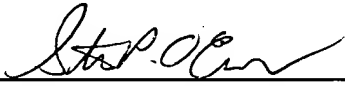
Director LeGuyader held that the restriction requirement should be viewed as a species election requirement, noting that the Applicants have now claimed the specific species, essentially electing a species on which prosecution has proceeded. By electing a species, Applicants are not required to limit the scope of their claims to that elected species, thus foregoing examination of other species in this application. Applicants are entitled to the full scope of their claims within the group elected in response to the restriction requirement. As Director LeGuyader reminds the Examiner, "[s]hould the elected species be found allowable over the art, the examiner will follow the guidelines in M.P.E.P. 803.02 for consideration of other species." The claims have been restored to their scope as of the time Applicants responded to the second restriction requirement. They are entitled to have the full scope of the claims examined.

For these reasons, Applicants request withdrawal of the restriction requirement, and examination of the full scope of claims 13, 26, 52-76, 78, 79, and 81-87 in this application. If the Office maintains the restriction requirement, Applicants request that the Office make it final so they may file a petition seeking review of that decision.

Please grant any extensions of time required to enter this Response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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